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PTO/SB/21 (08-00)

<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Serial Number	10/632,780	
	File Date	8/1/2003	
	First Named Inventor	Philipp	
	Group Art Unit		
	Examiner Name		
Total Number of Pages in this Submission		Attorney Docket Number	TUL2BUSA

**ENCLOSURES (check all that apply)**

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input type="checkbox"/> Other Enclosure(s) (please identify below):
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**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm or Individual Name	Mary E. Bak
Signature	<i>Mary E. Bak</i>
Date	October 29, 2003

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DOCKET NO.: TUL2BUSA  
CUSTOMER NO.: 00270

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of ) Group Art Unit:  
Mario T. Philipp )  
 ) Examiner:  
 )  
Appln. No. 10/632,780 )  
 )  
Filed: August 1, 2003 )  
 )  
For: SURFACE ANTIGENS AND PROTEINS )  
USEFUL IN COMPOSITIONS FOR THE )  
DIAGNOSIS AND PREVENTION OF )  
LYME DISEASE )

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

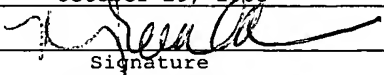
Sir:

Applicant submits to the Examiner the attached Form PTO/SB/08A/B document listing and this paper pursuant to 37 CFR § 1.56 and § 1.97-1.98. Form PTO/SB/08A/B and this paper identify documents previously cited in US Patent Application No. 09/445,803, filed December 13, 1999.

According to 37 CFR § 1.98(d), Applicant has not enclosed copies of any US patents, publications, or other documents listed herein, which listed items were previously cited by or submitted to the US Patent and Trademark Office in prior parent US Patent Application No. 09/445,803, filed

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December 13, 1999. The prior parent patent application is relied upon herein for an earlier priority date under 35 USC § 120.

#### REMARKS

Listed below are previously filed US Patent applications. These applications and the present application are commonly owned:

- (i) US Patent Application No. 09/445,803, filed 6/29/1998  
(US Patent Publication No. US-2003-0059894-A1, published 3/27/2003)
- (ii) US Provisional Patent Application No. 60/051,271 filed 6/30/1997, now abandoned

Listed below are documents cited in the International Search Report dated November 13, 1998 in the related International Patent Application No. PCT/US98/13551, filed June 29, 1998. A copy of the Report is enclosed.

- AF European Patent No. EP-465,204-A2, published 01/08/1992
- AAD ZHANG et al., "Antigenic Variation in Lyme Disease *Borrelia* by Promiscuous Recombination of VMP-like Sequence Cassettes", *Cell*, April 1997, 89(2):275-285
- AAE RAMAMOORTHY, "Molecular Characterization, Genomic Arrangement, and Expression of *bmpD*, a New Member of the *bmp* Class of Genes Encoding Membrane Proteins of *Borrelia burgdorferi*", *Infect. Immun.*, April 1996, 64(4):1259-1264

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- AAF ZHANG et al., "Kinetics and in vivo Induction of  
vlsE Antigenic Variation in *Borrelia*  
*burgdorferi*", EMBL/GenBank/DDBJ databases, June  
1998, Accession No. AF034515
- AAG KAWABATA et al., "Genetic and Immunological  
Analyses of Vls (VMP-like Sequences) in *Borrelia*  
*burgdorferi*", EMBL/GenBank/DDBJ databases, March  
1998 Accession No. AB011063
- AAH ZHANG et al., "Kinetics and in vivo Induction of  
vlsE Antigenic Variation in *Borrelia*  
*burgdorferi*", EMBL/GenBank/DDBJ databases, June  
1998, Accession No. AF034525
- AAI ZHANG et al., "Kinetics and in vivo Induction of  
vlsE Antigenic Variation in *Borrelia*  
*burgdorferi*", EMBL/GenBank/DDBJ databases, June  
1998, Accession No. AF034523

The month of publication for documents BBH, BBK, and  
BBP could not be determined. The years of publication for  
documents BBK and BBP are sufficiently earlier than the  
effective US filing date and/or the foreign priority date  
of the present application so that the particular month of  
publication of the document is not an issue (MPEP 609).

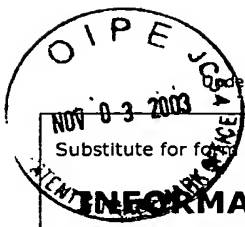
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The Examiner is respectfully requested to consider the documents identified in this paper and in the attached Form PTO/SB/08A/B during the course of examination of this application.

Respectfully submitted,

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Attorneys for Applicant

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/632,780
				Filing Date	August 1, 2003
				First Named Inventor	Philipp
				Group Art Unit	
				Examiner Name	
Sheet	1	Of	8	Attorney Docket Number	TUL2BUSA

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	A	US-6,437,116-B1	08-20-2002	NORRIS et al.	
	B	US-6,475,492-B1	11-02-2002	PHILIPP et al.	
	C	US-2003-0059894-A1	03-27-2003	PHILIPP	
	D	US-5,217,872	06-08-1993	DORWARD et al.	
	E	US-5,403,718	04-04-1995	DORWARD et al.	
	F	US-6,083,722-A	07-04-200	BERGSTROM et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	AA	WO-90/04411	05-03-1990	BERGSTROM et al.		
	AB	WO-91/13630	09-19-1991	SIMPSON et al.		
	AC	WO-91/09870	07-11-1991	FUCHS et al.		
	AD	WO-92/00055	01-09-1992	FLAVELL et al.		
	AE	EP-339,695-A	11-2-1989	BLOEMHOFF et al.		
	AF	EP-465,204-A2	01-08-1992	ACREE et al.		

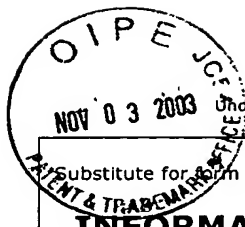
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				First Named Inventor	Philipp
				Group Art Unit	
				Examiner Name	
Sheet	2	of	8	Attorney Docket Number	TUL2BUSA

NONPATENT LITERATURE DOCUMENTS			
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	AAA	FIKRIG et al., Borrelia burgdorferi P35 and P37 Proteins, Expressed In Vivo, Elicit Protective Immunity, Immunity, May 1997, 6:531-539	
	AAB	ABERER, et al., Molecular Mimicry and Lyme Borreliosis: A Shared Antigenic Determinant Between Borrelia burgdorferi and Human Tissue, December 1989, 26:732-737	
	AAC	GASSMANN et al., N-Terminal Amino Acid Sequence of the Borrelia burgdorferi flagellin, FEMS Microbiol. Lett., July 1989, 60:101-106	
	AAD	ZHANG et al., Antigenic Variation in Lyme Disease Borrelia by Promiscuous Recombination of VMP-like Sequence Cassettes, Cell, April 1997, 89(2):275-285	
	AAE	RAMAMOORTHY, Molecular Characterization, Genomic Arrangement, and Expression of bmpD, a New Member of the bmp Class of Genes Encoding Membrane Proteins of Borrelia burgdorferi, Infect. Immun., April 1996, 64(4):1259-1264	
	AAF	ZHANG et al., Kinetics and in vivo Induction of vlsE Antigenic Variation in Borrelia burgdorferi, EMBL/GenBank/DDBJ databases, June 1998, Accession No. AF034515	
	AAG	KAWABATA et al., Genetic and Immunological Analyses of Vls (VMP-like Sequences) in Borrelia burgdorferi, EMBL/GenBank/DDBJ databases, March 1998, Accession No. AB011063	

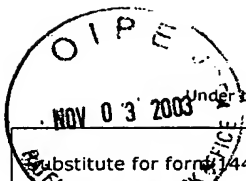
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STATEMENT BY APPLICANT**

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Sheet	3	of	8	Attorney Docket Number	TUL2BUSA
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**Complete if Known**

Application Number	10/632,780
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First Named Inventor	Philipp
Group Art Unit	
Examiner Name	

**NONPATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	AAH	ZHANG et al., Kinetics and in vivo Induction of vlsE Antigenic Variation in Borrelia burgdorferi, EMBL/GenBank/DDBJ databases, June 1998, Accession No. AF034525	
	AAI	ZHANG et al., Kinetics and in vivo Induction of vlsE Antigenic Variation in Borrelia burgdorferi, EMBL/GenBank/DDBJ databases, June 1998, Accession No. AF034523	
	AAJ	BARBOUR et al., Variation in a Major Surface Protein of Lyme Disease Spirochete, Infect. Immun., July 1984, 45:94-100	
	AAK	SIMPSON et al., Reactivity of Human Lyme Borreliosis Sera with a 39-Kilodalton Antigen Specific to Borrelia burgdorferi, J. Clin. Microbiol., June 1990, 28:1329-1337	
	AAL	HANSEN et al., Immunochemical Characterization of and Isolation of the Gene for a Borrelia burgdorferi Immunodominant 60-Kilodalton Antigen Common to a Wider Range of Bacteria, Infect. Immun., August 1988, 56:2047-2053	
	AAM	HANSEN et al., Measurement of Antibodies to the Borrelia burgdorferi Flagellum Improves Serodiagnosis in Lyme Disease, J. Clin. Microbiol., February 1988, 26:338-346	
	AAN	WILSKE et al., Immunochemical and Immunological Analysis of European Borrelia burgdorferi Strains, Zbl. Bakt. Hyg. A., December 1986, 263:92-102	

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Sheet	4	of	8	Attorney Docket Number	TUL2BUSA

NONPATENT LITERATURE DOCUMENTS

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	AAO	DORWARD et al., Immune Capture and Detection of Borrelia burgdorferi Antigens in Urine, Blood, or Tissues from Infected Ticks, Mice, Dogs and Humans, J. Clin. Microbiol., June 1991, 29:1162-1170	
	AAP	BAKKEN et al., Interlaboratory Comparison of Test Results for Detection of Lyme Disease by 516 Participants in the Wisconsin State Laboratory of Hygiene/College of American Pathologist Proficiency Testing Program, J. Clin. Microbiol., March 1997, 35:537	
	AAQ	DONAHUE et al., Reservoir Competence of White-Footed Mice for Lyme Disease Spirochetes, Am. J. Top. Med. Hyg., January 1987, 36:92-96	
	AAR	GREEN et al., Immunoblot Analysis of Immunoglobulin G Response to the Lyme Disease Agent (Borrelia burgdorferi) in Experimentally and Naturally Exposed Dogs, J. Clin. Micro., April 1988, 26:648-653	
	AAS	COX et al., Limited Surface Exposure of Borrelia burgdorferi Outer Surface Lipoproteins, Proc. Natl. Acad. Sci. USA, July 1996, 93:7973-7978	
	AAT	KAY et al., In vivo Hepatic Gene Therapy: Complete Albeit Transient Correction of Factor IX Deficiency in Hemophilia B Dogs, Proc. Natl. Acad. Sci. USA, March 1994, 91:2353	
	AAU	ISHIBASHI et al., Hypercholesterolemia in Low Density Lipoprotein Receptor Knockout Mice and its Reversal by Adenovirus-Mediated Gene Delivery, J. Clin. Invest., August 1993, 92:883	

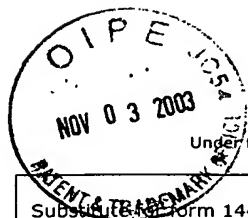
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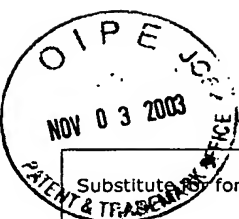
NONPATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	AAV	ZHANG et al., Kinetics and In Vivo Induction of Genetic Variation of vlsE in Borrelia burgdorferi, Infect. Immun., August 1998, 66(8):3689-3697	
	AAW	ZHANG, et al., Genetic Variation of the Borrelia burgdorferi Gene vlsE Involves Cassette-Specific, Segmental Gene Conversion, Infect. Immun., August 1998, 66:3698-3704	
	AAX	KOCHI et al., Facilitation of Complement-Dependent Killing of the Lyme Disease Spirochete, Borrelia burgdorferi, by Specific Immunoglobulin G Fab Antibody Fragments, Infect. Immun., June 1993, 61:2532-2536	
	AAY	REINITZ et al., Variable and Conserved Structural Elements of Trypanosome Variant Surface Glycoproteins, Mol. Biochem. Parasitol., February 1992, 51:119-132	
	AAZ	MARRACK et al., Subversion of the Immune System by Pathogens, Cell, January 1994, 76:323-332	
	BBA	GARRITY et al., Refocusing Neutralizing Antibody Response by Targeted Dampening of an Immunodominant Epitope, J. Immunol., July 1997, 159:279-289	
	BBB	LIGHTFOOT et al., Empiric Parenteral Antibiotic Treatment of Patients with Fibromyalgia and Fatigue and a Positive Serologic Result for Lyme Disease, September 1993, 129:503-509	
	BBC	TUGWELL et al., Laboratory Evaluation in the Diagnosis of Lyme Disease, Ann. Intern. Med., December 1997, 127:1109-1123	

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				Application Number	10/632,780
				Filing Date	August 1, 2003
				First Named Inventor	Philipp
				Group Art Unit	
				Examiner Name	
Sheet	6	of	8	Attorney Docket Number	TUL2BUSA

**NONPATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	BBD	FOREST et al., Assembly and Antigenicity of the Neisseria gonorrhoeae Pilus Mapped with Antibodies, Infec. Immun., February 1996, 64:644-652	
	BBE	KAWABATA et al., Genetic and Immunological Analyses of Vls (VMP-like Sequences) of Borrelia burgdorferi, Microb. Pathog., March 1998, 24:155-166	
	BBF	PHILIPP et al., Safety and Immunogenicity of Recombinant Outer Surface Protein A (OspA) Vaccine Formulations in the Rhesus Monkey, J. Spirochetel and Tick-borne Disease, March 1996, 3:67-79	
	BBG	DESILVA et al., Borrelia burgdorferi OspA is an Arthropod-specific Transmission-blocking Lyme Disease Vaccine, J. Exp. Med., January 1996, 183:271-276	
	BBH	MATHER et al., Ixodes Saliva: Vector Competence for Borrelia burgdorferi and Potential Vaccine Strategies, in VII International Congress on Lyme Borreliosis, San Francisco, CA, 1996	
	BBI	SADZIENE et al., Antibody-resistant Mutants of Borrelia burgdorferi: In Vitro Selection and Characterization, J. Exp. Med., September 1992, 176:799-809	
	BBJ	DESILVA et al., Growth and Migration of Borrelia burgdorferi in Ixodes Ticks During Blood Feeding, Am. J. Trop. Med., October 1995, 53:397-404	

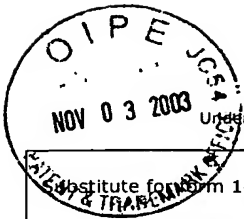
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	BBK	ROSA et al., Recombination between Genes Encoding Major Outer Surface Proteins A and B of Borrelia burgdorferi, Mol. Microbial., 1992, 6:3031-3040	
	BBL	SCHWAN et al., Distribution and Molecular Analysis of Lyme Disease Spirochetes, Borrelia burgdorferi, Isolated from Ticks throughout California, J. Clin. Microbiol., December 1993, 31:3096-3108	
	BBM	LIANG et al., Sensitive and Specific Serodiagnosis of Lyme Disease by Enzyme-Linked Immunosorbent Assay with a Peptide Based on an Immunodominant Conserved Region of Borrelia burgdorferi VlsE, J. Clin. Microbiol., December 1999, 37(12):3990-996	
	BBN	LIANG et al., Analysis of Antibody Response to Invariable Regions of VlsE, the Variable Surface Antigen of Borrelia burgdorferi, Infect. Immun., December 1999, 67(12):6702-6706	
	BBO	LIANG et al., An Immunodominant Conserved Region Within the Variable Domain of VlsE, the Variable Surface Antigen of Borrelia burgdorferi, J. Immunol., November 1999, 163(10):5566-5573	
	BBP	ABBAS, et al., Eds., Strategies for Vaccine Development in Cellular and Molecular Immunology, W.B. Saunders Company, Philadelphia, PA: p. 315, 1991	

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	BBQ	BOWIE, et al., Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions, Science, March 1990, vol. 247, pp. 1306-1310		
	BBR	BURGESS et al., Possible Dissociation of the Heparin-binding and Mitogenic Activities of Heparin-binding (Acidic Fibroblast) Growth Factor-1 from Its Receptor-binding Activities by Site-directed Mutagenesis of a Single Lysine Residue, J. Cell Biol, November 1990, vol. 111, pp. 2129-2138		
	BBS	LAZAR et al., Transforming Growth Factor Alpha: Mutation of Aspartic Acid 47 and Leucine 48 Results in Different Biological Activities, Mol Cell Biol, March 1988, vol. 8 No. 3, pp. 1247-1252		

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